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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,638	06/26/2006	Ljubomir Antoncic	21388/0209171-US0	8154
7278	7590	07/16/2010		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER SHIAO, REI TSANG	
			ART UNIT 1628	PAPER NUMBER
			MAIL DATE 07/16/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/584,638	<b>Applicant(s)</b> ANTONCIC ET AL.	
	<b>Examiner</b> REI-TSANG SHIAO	<b>Art Unit</b> 1628	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4-7, 11-15, 17-22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) 11-15, 17-22 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/26/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/26/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This application claims benefit of the foreign applications:  
SLOVENIA P-200300321 with a filing date 12/29/2003; and  
SLOVENIA P-200400022 with a filing date 01/23/2004.
2. Amendment of claims 4, 11, 15, 17-22 and 24, cancellation of claims 1-3, 8-10, 16 and 23, and addition of claims 25-26 in the amendment filed on 2/27/2009 is acknowledged. Claims 4-7, 11-15, 17-22 and 24-26 are pending in the application. No new matter has been found. Since the newly added claims 25-26 are commensurate within the scope of the invention, claims 4-7, 11-15, 17-22 and 24-26 are prosecuted in the case.

### ***Information Disclosure Statement***

3. Applicant's Information Disclosure Statement filed on June 26, 2006 has been considered. Please refer to Applicant's copy of the 1449 submitted herein.

### ***Responses to Election/Restriction***

4. Applicant's election without traverse of Group II claims 4-7 in the reply filed on February 27, 2009 is acknowledged.

Claims 4-7, 11-15, 17-22 and 24-26 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 4-7 are drawn to processes of making.

Claims 4-7 are prosecuted in the case. Claims 11-15, 17-22 and 24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

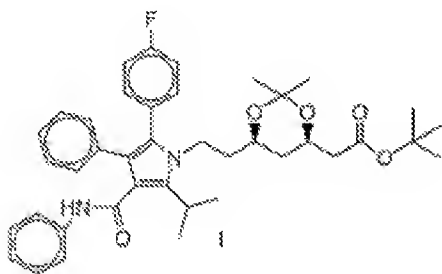
The requirement is still deemed proper and therefore is made FINAL.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the instant processes of making amorphous (4R-cis)-6-[2-[3-phenyl-4-(phenylcarbamoyl)-2-(4-fluorophenyl)-5-(1-methylethyl)-pyrrol-1-yl]-ethyl]-2,2-dimethyl-[1,3]-dioxane-4-yl-aceticacid-tertiary butyl ester (i.e., compound of formula (I)) using a starting material crystalline form I or form II of the compound of formula (I), i.e.,



, does not reasonably provide enablement for instant processes of making using a starting material crystalline of the compound of

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formula (I) without limitation (i.e., no named forms). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Dependent claims 4-7 are also rejected along with claim 1 under 35 U.S.C. 112, first paragraph.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

#### **The nature of the invention**

The nature of the invention is processes of making amorphous (4R-cis)-6- [2-[3-phenyl-4-(phenylcarbamoyl)-2-(4-fluorophenyl)-5-(1-methylethyl)-pyrrol-1-yl]-ethyl]-2,2-

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dimethyl-[1,3]-dioxane-4-yl-aceticacid-tertiary butyl ester (i.e., compound of formula (I)) using a starting material crystalline (4R-cis)-6- [2-[3-phenyl-4-(phenylcarbamoyl)-2-(4-fluorophenyl)-5-(1-methylethyl)-pyrrol-1-yl]-ethyl]-2,2-dimethyl-[1,3]-dioxane-4-yl-aceticacid-tertiary butyl ester, wherein the crystalline form is not limited (i.e., no named form), see claim 4.

**The state of the prior art and the predictability or lack thereof in the art**

The state of the prior art is Barkoczy et al. US 7,186,848, it discloses crystalline form I or II of compound of formula (I), see columns 1-10.

**The amount of direction or guidance present and the presence or absence of working examples**

The only direction or guidance present in the instant specification is that a form I or form II of the compound of formula (I), see lines 20-25 on page 6 of the specification. There is no data present in the instant specification, wherein the crystalline is not limited.

**The breadth of the claims**

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include any crystalline forms of compound of formula (I) , which are not limited.

**The quantity or experimentation needed and the level of skill in the art**

While the level of the skill in the chemical arts is high, it would require undue experimentation of one of ordinary skill in the art to resolve any crystalline forms of compound of formula (I), which are not limited. There is no guidance or working examples present for constitutional any crystalline forms of compound of formula (I), which are not limited. Incorporation of the limitation of the crystalline (i.e., form I or II) into claim 1 would overcome this rejection.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4, line 4, recites “crystalline (4R-cis)-6- [2-[3-phenyl-4-(phenylcarbamoyl)-2-(4-fluorophenyl)-5-(1-methylethyl)-pyrrol-1-yl]-ethyl]-2,2-dimethyl-[1,3]-dioxane-4-yl-aceticacid-tertiary butyl ester” without X-ray diffraction pattern data, is ambiguous and indefinite. It is noted that a fully X-ray diffraction pattern data is the fingerprint characteristics of a crystalline compound. Incorporation of an X-ray diffraction pattern data into claim 4 would obviate the rejection.

Dependent claims 5-7 are also rejected along with claim 4 under 35 U.S.C. 112, second paragraph.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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/REI-TSANG SHIAO /  
Primary Examiner, Art Unit 1628

June 29, 2010